

A TUBULAR PROSTHESIS

The present invention relates to a tubular prosthesis of the type that is radially deformable, comprising a lattice that is deformable between a retracted state of small diameter and an expanded state of larger diameter.

For various types of treatment, it is known to place a tubular prosthesis inside a blood vessel, whether a vein or an artery. Such tubular prostheses are generally referred to by the term "stent".

The prosthesis is brought to the inside of the vessel while it is in its retracted state, and then for positioning purposes, the prosthesis is expanded so as to press against the inside surface of the vessel. This expansion is performed either automatically because of the elasticity of the prosthesis lattice, or else under drive from an internal balloon being inflated, leading to plastic deformation of the material constituting the lattice.

It is difficult to ensure that the prosthesis is held axially within the vessel, i.e. in the long direction of the vessel, and the prosthesis runs the risk of being moved along the vessel under drive from the flow of blood. In addition, the prosthesis runs the risk of not being pressed exactly against the surface of the blood vessel, because of its irregular section.

In order to avoid such movement, it is known that the end of the metal lattice can present outwardly-projecting catches suitable for penetrating into the wall of the vessel so as to prevent the prosthesis from moving axially.

It is also known to secure the prosthesis to the wall of the vessel, e.g. by putting clips into place, which clips are fitted after the prosthesis has been put into place.

Those fastener means are not very reliable and they are difficult to put into place.

An object of the invention is to provide a tubular prosthesis which can be positioned reliably and which is relatively easy to put into place.

To this end, the invention provides a tubular
5 prosthesis of the above-specified type, characterized in that it includes at least two external hooks defining between them a clamp for hooking in external tissue, the two hooks being carried by the lattice and being movable between a spaced-apart position in which the clamp is
10 open, and a closer-together position in which the clamp is closed.

In particular embodiments, the tubular prosthesis includes one or more of the following characteristics:

- each hook is connected to the lattice from a
15 connection end, and the hooks of a given clamp are movable relative to each other during deformation of the prosthesis;

- the lattice comprises crossing wires that form meshes in the form of deformable quadrilaterals, and each
20 hook is connected to the lattice in a corner of a quadrilateral;

- each hook is welded or soldered to the lattice at its connection end;

- each hook is extended at its connection end by a
25 strand that is twisted around the lattice;

- each hook of a given clamp presents the shape of a shepherd's crook at its hooking end, the two hooks overlapping at least in part in order to form said clamp;

- each hook is in the form of a substantially
30 rectilinear blade, the two hooks extending facing each other and spaced apart from each other when the clamp is open; and

- the lattice is elastically deformable towards its expanded position.

35 The invention also provides a kit for treating a blood vessel, the kit being characterized in that it comprises:

- a prosthesis as defined above;
- means for holding the lattice in the retracted state in the region of the or each clamp; and
- a lattice-delivery tube defining a confinement duct for confining the prosthesis in its retracted state.

In a particular embodiment, the confinement duct of the delivery tube includes longitudinal channels for receiving the hooks.

The invention can be better understood on reading the following description given purely by way of example and made with reference to the drawings, in which:

- Figure 1 is a perspective view of a tubular prosthesis in the expanded state;
- Figure 2 is a section view on a larger scale showing the prosthesis in the expanded state in a region that includes a clamp;
- Figure 3A is a cross-section view of the prosthesis in the retracted state;
- Figure 3B is a perspective view of the prosthesis being implanted while in the retracted state of Figure 3;
- Figure 3C is a section view on a larger scale showing the prosthesis in the retracted state in a region that includes a clamp in the open position;
- Figure 4A is a view identical to that of Figure 3A showing the prosthesis expanded prior to hooking;
- Figure 4B is a perspective view of the expanded prosthesis prior to hooking;
- Figure 5A is a view identical to Figure 3A showing the prosthesis expanded and hooked after the clamp-retaining members have been withdrawn;
- Figure 5B is a perspective view of the expanded prosthesis after the clamp-retaining members have been withdrawn; and
- Figures 6 and 7 are perspective and elevation views of various embodiments of the prosthesis of the invention.

The tubular prosthesis 10 shown in Figure 1 is for putting into place in a blood vessel. It comprises a tubular lattice 12 that is embedded in a film 14 over substantially the entire length of the prosthesis. In
5 the vicinity of one of its ends, the prosthesis also comprises three clamps 16 that are angularly spaced apart regularly at its periphery.

Each clamp 16 is made up of two hooks 18 carried by the metal lattice 12. These hooks can be moved relative
10 to each other between a spaced-apart position in which the clamp is open, and a close-together position in which the clamp is closed.

The clamps 16 are provided on an end segment 20 of the prosthesis that does not have any film 14, the
15 lattice 12 thus not being covered in this region. In contrast, the main region of the prosthesis, referenced 22 has the lattice 12 embedded in the film 14.

The lattice 12 is made of stainless steel of biocompatible quality. For example, it is made by
20 braiding or knitting a wire, axially expanding a tube, or by any other suitable technique.

In the embodiment shown in Figure 1, the lattice 12 is constituted by two bundles of wires wound helically in opposite directions, the wires in any one bundle
25 generally extending parallel to one another and across the wires of the bundle of wires that are wound in the opposite direction.

The wires in the two oppositely-wound bundles cross over and under one another in alternation.

30 The lattice 12 is preferably elastically deformable to expand radially between a small diameter retracted state and a larger diameter expanded state.

In its expanded state, shown in Figure 1, the meshes of the lattice form lozenges that are generally elongate
35 in the circumferential direction. In contrast, and as shown in Figure 3B, when the prosthesis is in the

retracted state, the meshes form lozenges that are elongate parallel to the axis of the prosthesis.

In a variant, the prosthesis is plastically deformable, i.e. the lattice presents a first stable
5 shape of small diameter and a second stable shape of larger diameter.

Over its segment 22, the lattice 12 is completely embedded in the film 14. This film is constituted by a material that is stretchable and liquid-proof, and it
10 fills the meshes.

This material is sufficiently stretchable to enable the film 14 to follow the deformation of the lattice from its retracted state to its expanded state without tearing or becoming unstuck, and in spite of the meshes of the
15 lattice deforming. Suitable materials are biocompatible elastomers such as a natural or synthetic rubber or indeed a biocompatible polymer such as a polyurethane.

The lattice 12 can be coated with the film 14 by a co-extrusion technique or a dipping technique, after the
20 metal has been degreased and treated with a bonding primer.

As shown in Figure 2, each of the hooks 18 forms a metal wire segment having a free end that is curved outwards to form the shape of a shepherd's crook 24. The
25 crook 24 extends a rectilinear segment 26. The hooks 18 overlap at least in part in order to form a clamp 16.

At its end opposite from the crook 24, each segment 26 is bonded to the metal lattice 12 in the opposite corners of a mesh by weld or solder tacking 28, visible
30 in Figure 1. The crooks 24 project outwards from the tubular segment defined by the lattice 12, and, at rest, the curved ends of the crooks lie in a plane extending transversely to the tubular prosthesis, i.e. perpendicular to its general axis, as can be seen in
35 Figure 2.

The diameter of the crooks 24 forming the hooks lies in the range 0.5 millimeters (mm) to 4 mm, whereas the

length of the arms 26 lies in the range 3 mm to 12 mm. The crooks 24 forming the curved ends of the hooks preferably have a diameter lying in the range one-fourth to one-eighth the length of the arm 26 of the hook.

5 The length of the arms 26 is such that when the prosthesis is in the expanded state as shown in Figure 1, the two crooks of the hooks 18 are moved towards each other and together define a loop that is closed or practically closed.

10 Initially, and as shown in Figures 3A, 3B, and 3C, the prosthesis is associated with means 30 for retaining the clamps 16 in the open position.

15 In addition, the prosthesis having its clamps held open is received in conventional manner in a delivery tube 32, within which the prosthesis is confined in its retracted state.

20 Advantageously, the inside duct of the tube 32 presents longitudinal channels 33 for receiving the ends of the hooks 18 that project from the generally tubular surface of the metal lattice.

25 As shown in Figures 3B and 3C, each means for holding a clamp open comprises a flexible tube 34, e.g. made of polyether ether ketone (PEEK). The tube 34 extends longitudinally between a distal end 36 for being received in the blood vessel, and a proximal end 38 designed to be accessible to the surgeon outside the body of the patient. Thus, the tube 34 may be about 1 meter (m) long.

30 A retaining opening 40 is provided in the side of the tube 34 generally in register with the associated clamp 16. The tube 34 is also fitted, in the vicinity of its proximal end 38, with a hollow side branch 42 fitted with a ring 43 for axially locking a sliding thread.

35 The releasable retaining means 30 also comprise a retaining rod 44 engaged axially in the tube 34, and a retaining thread 46 going round the mesh of the prosthesis that carries the clamp 16.

The retaining rod 44 extends from one end of the tube 34 to the other. It projects out from the tube at the proximal end 38.

5 This rod is movable inside the tube 34 between a retaining position in which the rod faces the opening 40 and a release position in which the rod 44 is spaced apart from the opening 40 and is offset towards the proximal end of the tube 34.

10 The retaining thread 46 comprises a single strand having an eyelet 48, a tightening loop 50, and a control segment 52 that extends along the entire length of the tube 34 from the opening 40 to the branch connection 42 from which it projects after passing through a locking ring 43.

15 The end eyelet 48 is constituted by a closed loop of small diameter through which the rod 44 is initially engaged when it is in its retaining position. The tightening loop 50 is formed by a strand segment engaged slidably through two meshes of the lattice adjacent to
20 the mesh carrying the clamp 16.

The tightening loop passes through the opening 40 to join the eyelet 48 at one end and the control segment 52 at its other end. The active length of the tightening loop 50 is variable as a function of the traction exerted
25 on the control segment 52, so that it controls the shape of the mesh carrying the clamp 16, as explained below.

Initially, prior to being put into place, the prosthesis is placed in the delivery tube 32, and the control segments 52 of the clamp-retaining means are
30 under tension such that the clamps are held open, as shown in Figure 3B. In this position, the tightening loop 50 tightens the mesh carrying the clamp so that the lozenge defining the mesh is elongate along its diagonal that is parallel to the axis of the prosthesis.

35 To put the prosthesis into place, it is inserted together with the tube 32 into the delivery zone, and then the tube 32 is withdrawn, thereby releasing the

prosthesis. The prosthesis expands and then becomes pressed against the inside surface of the blood vessel, as shown in Figures 4A and 4B.

5 During this expansion, the meshes of the prosthesis lattice extend because of the elasticity of the lattice so that the peripheral diagonal of the prosthesis lengthens, thus enabling the diameter of the prosthesis to be increased. In contrast, the meshes carrying clamps remain contracted, as shown in Figure 4B, because of the
10 tightening loops 50. Thus, the clamps 16 are docked against the surface of the blood vessel while they are still in the open position.

By acting on the locking ring 43, the practitioner then proceeds to release the retaining thread so as to
15 allow the meshes carrying the clamps to deform elastically, thereby causing pairs of opposite hooks to move towards each other, closing each clamp, and causing the hooks to penetrate into the wall defining the blood vessel, as shown in Figures 5A and 5B.

20 After the retaining threads 46 have been released, the rod 44 is brought into the release position, such that the eyelet 48 is released from the rod 44. The practitioner then pulls on the control segment 52, enabling the retaining thread to escape from the metal
25 lattice, traveling through the two meshes adjacent to the mesh carrying the clamp.

Thus, since the clamp-retaining means have been made independent of the prosthesis, they can be extracted along an endoluminal path.

30 It will be understood that such a prosthesis is held effectively against the inside surface of the vessel by the presence of the clamps being held elastically in the closed position under drive from the prosthesis. In addition, since the clamps are closed simultaneously with
35 the prosthesis being put into place, it is relatively easy to install such a prosthesis.

Figure 6 shows a variant embodiment of a prosthesis of the invention.

The vascular prosthesis shown in Figure 6 comprises a lattice 100 itself made up of eight elastic metal
 5 wires, such as the wires F1, F2, and F3, that are twisted together in a manner that is described in greater detail below. Along the length of the lattice, these wires define a plurality of successive regions, which going downwards in Figure 6 are as follows:

- 10 · an end zone 102 having eight loops 104;
- successive regions 106, each presenting peripheral rings of twisted nodes 108;
- an end region 111 having end twists 112.

Considering the wire F1:

- 15 · the loop 104 is constituted by the wire F1 twisted into a loop over at least half a turn; and
- each node 108 is constituted by a twist of the wire F1 together with an adjacent wire such as F2 or F3 over one or more turns.

20 Thus, on either side of each double-twisted node referenced 115 where the wire is twisted through an even number of half-turns, and in particular through two half-turns, each wire strand forming the node extends in two directions that are parallel to each other and close
 25 together.

In contrast, with so-called triple-twisted nodes 117 where the wire is twisted through an odd number of half-turns, in particular three half-turns, each wire leaves in two directions that form between them an angle that is
 30 much less than 180° , for example a right angle or even an acute angle as shown, so as to constitute two adjacent sides of one of the meshes of the lattice.

As shown in Figure 6, in the example shown, the wire F1 starts from a twist 112 and then forms successively a
 35 node 115, a node 117, a node 115, another node 115, a node 117, a node 115, another node 115, a loop 113, a node 115, another node 115, a node 117, a node 115,

another anode 115, a node 117, a node 115, and another twist 112.

In this embodiment, each clamp referenced 116 is formed by a single metal wire 120 whose middle portion is engaged and twisted around wires defining the lattice, and whose two free ends are curved outwards to form hooks 118.

More precisely, the wire 120 is twisted from a node 115 about two angularly offset strands that diverge. Each branch of the wire 120 is then twisted with the following twisted node and thereafter extends transversely along a mesh diameter, the two arms meeting by extending parallel to each other towards respective curved ends.

Thus, as in the preceding embodiment, it is deformation of the mesh carrying the clamp that causes the clamp to open or close, the two arms with curved ends moving relative to each other.

In the embodiment of Figure 7, the hooks 218 are formed by simple, generally-rectilinear rods, each having one end secured to the end of a mesh and its other end projecting outwards a little from the generally cylindrical outside surface of the lattice.

In this embodiment, when the meshes are open, the pointed ends of two hooks 218 overlap. However, when the two adjacent meshes disposed on either side of the mesh carrying the clamp are closed, then the hooks are spaced apart from each other.

In order to put such a prosthesis into place, it is necessary to have two means for holding meshes closed for each of the clamps. Initially, they are applied to the two adjacent meshes so as to enable the clamp to be held open. After the prosthesis has been properly positioned, the two adjacent meshes are released, thereby leading to the clamp closing and the two hooks penetrating into the wall of the blood vessel.